



# 3

GP/1645

PATENT

ATTORNEY DOCKET NO. 06132/037002

Certificate of Mailing: Date of Deposit: May 3, 2002

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry  
Printed name of person mailing correspondence

*Susan M. Barry*  
Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Harold Kleanthous et al.	Art Unit:	1645
Serial No.:	10/039,183	Examiner:	Not Yet Assigned
Filed:	January 3, 2002	Customer No.:	21559
Title:	Helicobacter GHPO 1360 and GHPO 750 Polypeptides and Corresponding Polynucleotide Molecules		

Assistant Commissioner For Patents  
Washington, DC 20231

TECH CENTER 1600/2900

MAY 10 2002

RECEIVED

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449.

Submission of this statement is not a representation that a search has been made, nor is information included in this statement an admission that the information is material to patentability.

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application serial number 08/831,310, filed on April 1, 1997. The following references were submitted to and/or cited by the Office in the prior application and, therefore, copies of these references are not provided in this application:

MAY 15 2002  
S 200/740  
RECEIVED

5,116,821	05/26/92	Randall et al.
5,128,140	07/07/92	Chapura et al.
5,258,178	11/02/93	Cordle et al.
5,447,923	09/05/95	Catrenich et al.
5,476,669	12/19/95	Borody
5,514,660	05/07/96	Zopf et al.
5,538,729	07/23/96	Czinn et al.
5,563,039	10/08/96	Goeddel et al.
5,567,594	10/22/96	Calenoff
5,610,060	03/11/97	Ward et al.
5,620,964	04/15/97	Roth et al.
5,679,769	10/21/97	Danishefsky et al.
5,753,630	05/19/98	Zopf et al.
WO 91/09049	27.06.91	PCT
WO 93/18150	16.09.93	PCT
WO 94/09823	11.05.94	PCT
WO 95/22987	31.08.95	PCT
WO 95/33482	14.12.95	PCT
WO 96/33732	31.10.96	PCT
WO 96/38475	05.12.96	PCT
WO 96/40893	19.12.96	PCT
WO 97/03359	30.01.97	PCT

WO 97/03360	30.01.97	PCT
WO 97/19098	29.05.97	PCT
WO 97/11182	27.03.97	PCT
WO 97/12908	10.04.97	PCT
WO 97/12909	10.04.97	PCT
WO 97/37044	09.10.97	PCT
WO 98/18323	07.05.98	PCT

Borén et al., “Attachment of *Helicobacter pylori* to Human Gastric Epithelium Mediated by Blood Group Antigens,” *Science* 262:1892-1895 (1993).

Borody et al., “Omeprazole Enhances Efficacy of Triple Therapy in Eradicating *Helicobacter pylori*,” *Gut* 37:477-481 (1995).

Clayton et al., “Sensitive Detection of *Helicobacter pylori* by Using Polymerase Chain Reaction,” *Journal of Clinical Microbiology* 30:192-200 (1992).

Czinn et al., “Oral Immunization Against Helicobacter Pylori,” *Infection and Immunity* 59:2359-2363, 1991.

Doig et al., “Identification of Surface-Exposed Outer Membrane Antigens of *Helicobacter pylori*,” *Infection and Immunity* 62:4526-4533 (1994).

Drouet et al., “Partial Characterization of an External Polysaccharide of *Helicobacter pylori* by Using an Immunoglobulin M Monoclonal Antibody,” *Infection and Immunity* 61:2732-2736 (1993).

Fauchere et al., “Adherence of *Helicobacter pylori* Cells and Their Surface Components to HeLa Cell Membranes,” *Microbial Pathogenesis* 9:427-439 (1990).

Ferrero et al., “Recombinant Antigens Prepared from the Urease Subunits of *Helicobacter* spp.: Evidence of Protection in a Mouse Model of Gastric Infection,” *Infection and Immunity* 62:4981-4989 (1994).

Graham et al., “Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing,” *Annals of Internal Medicine* 115:266-269 (1991).

Haas et al., "TnMax- a Versatile Mini-Transposon for the Analysis of Cloned Genes and Shuttle Mutagenesis," Gene 130:23-31 (1993).

Husson et al., "Iron Acquisition by *Helicobacter pylori*: Importance of Human Lactoferrin," Infection and Immunity 61:2694-2697 (1993).

Illingworth et al., "Siderophore Production and Iron-Regulated Envelope Proteins of *Helicobacter pylori*," Zbl. Bakt. 280:113-119 (1993).

Kaplan, "Autogenous Vaccination Against *Helicobacter pylori*," South African Medical Journal 83:922-923 (1993).

Lee et al., "Oral Immunization with Recombinant *Helicobacter pylori* Urease Induces Secretory IgA Antibodies and Protects Mice from Challenge with *Helicobacter felis*," The Journal of Infectious Diseases 172:161-172 (1995).

Mohammadi et al., "*Helicobacter*-Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," Journal of Immunology 156:4729-4738 (1996).

Monath et al., "Development of Recombinant *Helicobacter pylori* Urease as an Oral Vaccine: Current Status," Gut 37(Supp 1):A52 (1995).

Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," Gut 39(Supp 2):A94 (1996).

Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against *Helicobacter pylori*," Eur. J. Clin. Microbiol. Infect. Dis. 14:391-399 (1995).

Robinson et al., "Protection against a Lethal Influenza Virus Challenge by Immunization with a Haemagglutinin-Expressing Plasmid DNA," Vaccine 11:957-960 (1993).

Robinson et al., "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," Vaccine 93, Cold Spring Harbor Laboratory Press, 311-315 (1993).

Sherburne et al., "*Helicobacter pylori* Expresses a Complex Surface Carbohydrate, Lewis X," Infection and Immunity 63:4564-4568 (1995).

Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of *Helicobacter pylori*," Scand. J. Gastroenterol. 28:934-938 (1993).

Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen *Helicobacter pylori*," Nature 388:539-547 (1997).

Ulmer et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259:1745-1749 (1993).

Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiological Hungarica 38:164-165 (1991).

Lee et al., U.S. Serial No. 08/568,122, filed December 6, 1995.

Haas et al., U.S. Serial No. 10/013,315, filed November 5, 2001.

Kleanthous et al., U.S. Serial No. 08/834,666, filed April 1, 1997.

Haas et al., U.S. Serial No. 08/834,705, filed April 1, 1997.

Haas et al., U.S. Serial No. 09/988,067, filed November 16, 2001.

Kleanthous et al., U.S. Serial No. 09/881,752, filed June 15, 2001.

Kleanthous et al., U.S. Serial No. 09/895,913, filed June 29, 2001.

If there are any other charges or any credits, please apply them to Deposit Account  
No.03-2095.

Respectfully submitted,

Date: May 3, 2002

Susan M. Michaud  
Susan M. Michaud, Ph.D.  
Reg. No. 42,885

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045  
06132.037002 Information Disclosure Statement.wpd



RECEIVED  
MAY 10 2002  
TECH CENTER 1600/2000 I P E JC59

SUBSTITUTE FORM PTO-1449  
(MODIFIED) U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Sheet 1 of 5

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Attorney Docket No.	06132/037002
(37 CFR §1.98(b))	Serial No.	10/039,183
	Applicant	Kleanthous et al.
	Filing Date	January 3, 2002
	Group	Not Yet Assigned
	IDS Filed	May 3, 2002
	Customer No.	21559

U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	5,116,821	05/26/92	Randall et al.			
	5,128,140	07/07/92	Chapura et al.			
	5,258,178	11/02/93	Cordle et al.			
	5,447,923	09/05/95	Catrenich et al.			
	5,476,669	12/19/95	Borody			
	5,514,660	05/07/96	Zopf et al.			
	5,538,729	07/23/96	Czinn et al.			
	5,563,039	10/08/96	Goeddel et al.			
	5,567,594	10/22/96	Calenoff			
	5,610,060	03/11/97	Ward et al.			
	5,620,964	04/15/97	Roth et al.			
	5,679,769	10/21/97	Danishefsky et al.			
	5,753,630	05/19/98	Zopf et al.			
	5,837,240	11/17/98	Lee et al.			
	5,972,336	10/26/99	Michetti et al.			
	6,290,962 B1	09/18/01	Michetti et al.			

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

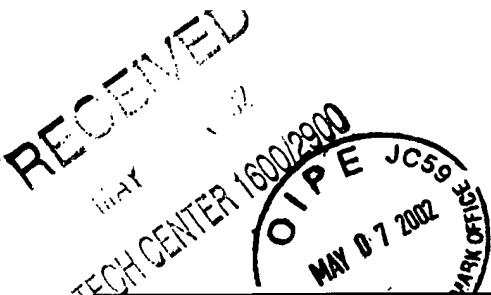
RECEIVED

MAY 10 2002

100-9290 E JC59  
MAY 11 2002

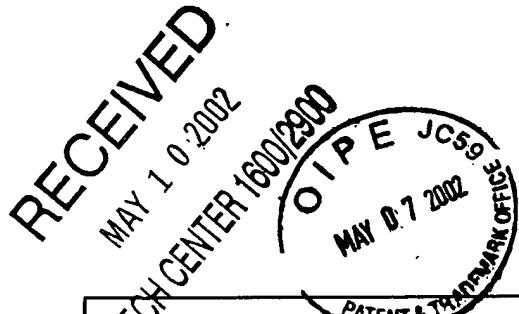
Sheet 2 of 5

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				Attorney Docket No.	06132/037002	
				Serial No.	10/039,183	
				Applicant	Kleanthous et al.	
				Filing Date	January 3, 2002	
				Group	Not Yet Assigned	
				IDS Filed	May 3, 2002	
				Customer No.	21559	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)						
(37 CFR §1.98(b))						
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION						
	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	WO 91/09049	27.06.91	PCT			
	WO 93/18150	16.09.93	PCT			
	WO 94/09823	11.05.94	PCT			
	WO 95/22987	31.08.95	PCT			
	WO 95/33482	14.12.95	PCT			
	WO 96/33732	31.10.96	PCT			
	WO 96/38475	05.12.96	PCT			
	WO 96/40893	19.12.96	PCT			
	WO 97/03359	30.01.97	PCT			
	WO 97/03360	30.01.97	PCT			
	WO 97/19098	29.05.97	PCT			
	WO 97/11182	27.03.97	PCT			
	WO 97/12908	10.04.97	PCT			
	WO 97/12909	10.04.97	PCT			
	WO 97/37044	09.10.97	PCT			
	WO 98/18323	07.05.98	PCT			
EXAMINER				DATE CONSIDERED		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.						



Sheet 3 of 5

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE	Attorney Docket No.	06132/037002
			Serial No.	10/039,183
			Applicant	Kleanthous et al.
			Filing Date	January 3, 2002
			Group	Not Yet Assigned
			IDS Filed	May 3, 2002
			Customer No.	21559
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)</b>				
Borén et al., "Attachment of <i>Helicobacter pylori</i> to Human Gastric Epithelium Mediated by Blood Group Antigens," <i>Science</i> 262:1892-1895 (1993).				
Borody et al., "Omeprazole Enhances Efficacy of Triple Therapy in Eradicating <i>Helicobacter pylori</i> ," <i>Gut</i> 37:477-481 (1995).				
Clayton et al., "Sensitive Detection of <i>Helicobacter pylori</i> by Using Polymerase Chain Reaction," <i>Journal of Clinical Microbiology</i> 30:192-200 (1992).				
Czinn et al., "Oral Immunization Against Helicobacter Pylori," <i>Infection and Immunity</i> 59:2359-2363, 1991.				
Doig et al., "Identification of Surface-Exposed Outer Membrane Antigens of <i>Helicobacter pylori</i> ," <i>Infection and Immunity</i> 62:4526-4533 (1994).				
Drouet et al., "Partial Characterization of an External Polysaccharide of <i>Helicobacter pylori</i> by Using an Immunoglobulin M Monoclonal Antibody," <i>Infection and Immunity</i> 61:2732-2736 (1993).				
Fauchere et al., "Adherence of <i>Helicobacter pylori</i> Cells and Their Surface Components to HeLa Cell Membranes," <i>Microbial Pathogenesis</i> 9:427-439 (1990).				
Ferrero et al., "Recombinant Antigens Prepared from the Urease Subunits of <i>Helicobacter</i> spp.: Evidence of Protection in a Mouse Model of Gastric Infection," <i>Infection and Immunity</i> 62:4981-4989 (1994).				
Graham et al., "Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing," <i>Annals of Internal Medicine</i> 115:266-269 (1991).				
Haas et al., "TnMax- a Versatile Mini-Transposon for the Analysis of Cloned Genes and Shuttle Mutagenesis," <i>Gene</i> 130:23-31 (1993).				
Husson et al., "Iron Acquisition by <i>Helicobacter pylori</i> : Importance of Human Lactoferrin," <i>Infection and Immunity</i> 61:2694-2697 (1993).				
Illingworth et al., "Siderophore Production and Iron-Regulated Envelope Proteins of <i>Helicobacter pylori</i> ," <i>Zbl. Bakt.</i> 280:113-119 (1993).				
Kaplan, "Autogenous Vaccination Against <i>Helicobacter pylori</i> ," <i>South African Medical Journal</i> 83:922-923 (1993).				
Lee et al., "Oral Immunization with Recombinant <i>Helicobacter pylori</i> Urease Induces Secretory IgA Antibodies and Protects Mice from Challenge with <i>Helicobacter felis</i> ," <i>The Journal of Infectious Diseases</i> 172:161-172 (1995).				
EXAMINER		DATE CONSIDERED		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.				



Sheet 4 of 5

SUBSTITUTE FORM PTO-146 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE		Attorney Docket No.	06132/037002
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/039,183
(37 CFR §1.98(b))		Applicant	Kleanthous et al.
		Filing Date	January 3, 2002
		Group	Not Yet Assigned
		IDS Filed	May 3, 2002
		Customer No.	21559
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)</b>			
	Mohammadi et al., "Helicobacter-Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," Journal of Immunology 156:4729-4738 (1996).		
	Monath et al., "Development of Recombinant <i>Helicobacter pylori</i> Urease as an Oral Vaccine: Current Status," Gut 37(Supp 1):A52 (1995).		
	Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," Gut 39(Supp 2):A94 (1996).		
	Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against <i>Helicobacter pylori</i> ," Eur. J. Clin. Microbiol. Infect. Dis. 14:391-399 (1995).		
	Robinson et al., "Protection against a-Lethal Influenza Virus Challenge by Immunization with a Haemagglutinin-Expressing Plasmid DNA," Vaccine 11:957-960 (1993).		
	Robinson et al., "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," Vaccine 93, Cold Spring Harbor Laboratory Press, 311-315 (1993).		
	Sherburne et al., "Helicobacter pylori Expresses a Complex Surface Carbohydrate, Lewis X," Infection and Immunity 63:4564-4568 (1995).		
	Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of <i>Helicobacter pylori</i> ," Scand. J. Gastroenterol. 28:934-938 (1993).		
	Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen <i>Helicobacter pylori</i> ," Nature 388:539-547 (1997).		
	Ulmer et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259:1745-1749 (1993).		
	Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiologica Hungarica 38:164-165 (1991).		
EXAMINER	DATE CONSIDERED		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.			

RECEIVED  
MAY 10 2002  
TECH CENTER 1600/2000  
O P E J C S E  
MAY 07 2002  
SUBSTITUTE FORM PTO-1449, DEPARTMENT OF COMMERCE  
(MODIFIED)

Sheet 5 of 5

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Attorney Docket No.	06132/037002
(37 C.F.R. §1.98(b))		Serial No.	10/039,183
		Applicant	Kleanthous et al.
		Filing Date	January 3, 2002
		Group	Not Yet Assigned
		IDS Filed	May 3, 2002
		Customer No.	21559
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)			
	Lee et al., U.S. Serial No. 08/568,122, filed December 6, 1995.		
	Haas et al., U.S. Serial No. 10/013,315, filed November 5, 2001.		
	Kleanthous et al., U.S. Serial No. 08/834,666, filed April 1, 1997.		
	Haas et al., U.S. Serial No. 08/834,705, filed April 1, 1997.		
	Haas et al., U.S. Serial No. 09/988,067, filed November 16, 2001.		
	Kleanthous et al., U.S. Serial No. 09/881,752, filed June 15, 2001.		
	Kleanthous et al., U.S. Serial No. 09/895,913, filed June 29, 2001.		
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.			